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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,558	07/13/2005	Richard Frank Tester	08830-0307US1	2680
23973 7590 01/21/2010 DRINKER BIDDLE & REATH ATTN: INTELLECTUAL PROPERTY GROUP ONE LOGAN SQUARE 18TH AND CHERRY STREETS PHILADELPHIA, PA 19103-6996				
EXAMINER				
PALENIK, JEFFREY T				
ART UNIT		PAPER NUMBER		
1615				
MAIL DATE		DELIVERY MODE		
01/21/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/517,558

**Applicant(s)**

TESTER ET AL.

**Examiner**

Jeffrey T. Palenik

**Art Unit**

1615

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3-12, 25-29, 36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) 6, 26-29 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 7-12, 25 and 36 is/are rejected.
- 7) ☒ Claim(s) 36 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

**STATUS OF APPLICATION**

Receipt is acknowledged of Applicants' Request for Continued Examination (RCE), Amendments and Remarks filed, 29 October 2009 in the matter of Application N° 10/517,558. Said filings are now entered on the record. The Examiner further acknowledges the following:

Claims 16-19 are newly cancelled.

No claims have been added.

Claim 1 has been amended to include the limitation wherein the product is in the form of a freeze-dried matrix. Support for the amendment is provided. In view of the amendment made to claim 1, the Examiner has reconsidered the withdrawal of claim 36 from consideration. Claim 36 is hereby rejoined for consideration on the merits. Claim 25 has also been amended to include the process of hydrolyzing as a means for obtaining  $\beta$ -limit dextrin from a waxy starch. Support is found in the original claims 23 and 25.

Thus, claims 1, 3-5, 7-12, 25 and 36 now represent all claims currently under consideration.

**INFORMATION DISCLOSURE STATEMENT**

No new Information Disclosure Statement (IDS) have been submitted for consideration.

#### **WITHDRAWN OBJECTIONS/REJECTIONS**

##### **Rejection under 35 USC 112**

Applicants' amendment to claim 25 providing antecedent basis for the claim to claim 1 is sufficient enough to render moot the rejection under 35 USC 112, second paragraph. Thus, said rejections have been **withdrawn**.

##### **Rejection under 35 USC 103(a)**

Applicants' amendment to claim 1 adding the "freeze-dried matrix" limitation is sufficient enough to render moot the rejection to claims 1, 3-5, 7-12 and 25, under 35 USC 103(a), as being unpatentable over the combined teachings of Kaper et al. (EP 0 242 913 A2) and Burgoyne et al. (USPN 6,046,185). Since a teaching of this process/structural limitation is absent, the combined references no longer render obvious the instantly amended claims. Said rejection now stands **withdrawn**.

#### **NEW OBJECTIONS/REJECTIONS**

In light of Applicants' amendments, most notably to claim 1, as well as the withdrawn rejections above, the following objection(s) and rejection(s) have been newly added:

#### **CLAIM OBJECTIONS**

Newly rejoined claim 36 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants are required to cancel the claim, or amend the claim to place the claim in proper dependent

form, or rewrite the claim in independent form. Claim 1, from which claim 36 depends, already recites that the formulation is freeze-dried or lyophilized. As such, the limitations recited in claim 36 duplicate those recited in the base claim.

### **CLAIM REJECTIONS - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-5, 7, 25 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ameraal et al. (USPN 5,482,560).

Amended claim 1 is directed to a bioadhesive pharmaceutical formulation comprising an active agent and a mucoadhesive carrier for said agent wherein said carrier is  $\beta$ -limit dextrin (BLD) and wherein said formulation is in the form of a freeze-dried (lyophilized) matrix. Claim 36, as discussed above, is interpreted by the Examiner as reciting the same limitations as claim 1. Claim 3 further limits the active agent to a pharmaceutically active agent. The composition is recited as being in the form of a buccal-melt product (claim 4) which is further limited to a wafer (claim 5) and also recited as a thin-film (claim 7). Herein, and for the purposes of examination on the merits, the Examiner broadly and reasonably interprets a wafer as being a form of or species of a thin film. Claim 25 recites that the  $\beta$ -limit dextrin of claim 1 is obtained by hydrolyzing a waxy starch.

The invention to Ameraal expressly teaches producing BLD by first forming an aqueous slurry of dull waxy (duwx) starch followed by using well-known drying techniques to recover the final product. Freeze-drying is one such technique that is used (col. 2, lines 47-60). Concerning the remaining limitations of claim 1, the invention of Ameraal is also directed to uses of BLD, specifically teaching that BLD's originating from dull waxy starch are more soluble and stable in aqueous solutions than conventional  $\beta$ -limit dextrin compounds thereby making them excellent carriers (Abstract). Ameraal further discloses that the practiced BLDs, while being very soluble, are useable for slow-release of different compounds such as sweeteners and drugs (col. 1, lines 63-67). Regarding the structural limitations for the final product recited in claims 4, 5 and 7, the reference also teaches that

BLD, in addition to being useful as a carrier for volatile ingredients (e.g. drugs, evaporative compounds) is also useful in extruded products as well as being useful as a thickener in gum candies (col. 1, lines 47-52).

Though it is not expressly stated that the products comprising the  $\beta$ -limit dextrans produced by Ameraal are made into thin film/wafer-shaped buccal melts, the teachings of Ameraal would have rendered such a concept *prima facie* obvious to a person of ordinary skill at the time the instant invention was conceived. Ameraal teaches and suggests using the aforementioned BLD as a carrier for such orally administered compounds as sweeteners and drugs. It is also suggested that such compositions may be used in oral products which are produced via extrusion, which further suggests to the ordinarily skilled artisan that such products are at one point malleable and can be made to take on any shape. As such, it is the position of the Examiner that the aforementioned product structure limitations are a design choice within the purview of the artisan to select.

Thus, based on the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, alone or in combination, especially in the absence of evidence to the contrary.

Claims 1, 8-12 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kono et al. (USPN 4,748,032).

The limitations of the amended claim 1 and claim 36 are discussed above. Concerning the limitation of “active agent”, the Examiner interprets said phrase in light of Applicants’ definition provided in the instant disclosure (see pg. 13, lines 1-6) as broadly and as reasonably as any agent (see MPEP §2111), such as one which has a flavor or nutritional value to it. Claims 8-10 recite the composition of claim 1 as further comprising at least one carbohydrate in the form of alginate, pectin or either of their derivatives. Claims 11 and 12 recite weight percent limitations of alginate within the composition.

The invention of Kono is directed to a method for preserving edible (e.g. food) compounds by encapsulating said compounds in a formulation comprising oligosaccharide-based components (Abstract). A solution form of the oligosaccharide is taught as being prepared from which a dry, powder form is achieved by using such well-known techniques as freeze-drying (col. 3, lines 41-45). Kono further teaches that said oligosaccharides are added depending on the kind and properties of the food of interest and usually ranges from 3 to 50 wt% based on the weight of the food (col. 3, lines 54-58). The oligosaccharides which are used by Kono are taught as being effective preservatives when used alone and even more effective when used in combination; such pairings including  $\beta$ -limit dextrin and sodium alginate (col. 3, lines 59-67).

The reference does not expressly teach the compositional ranges of alginate or alginate derivatives, as claimed by Applicants. Since the values and formats of each parameter with respect to the claimed composition are adjustable, it follows that each is a result-effective



parameter that a person having ordinary skill in the art would routinely optimize.

Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. In the instant case, Kono expressly teaches that 1.) the oligosaccharide(s) are more effective when employed in concert, 2.) the oligosaccharide(s) may comprise as high as 50 wt% of the composition per weight of the food preserved, and 3.) the amount will vary depending on the kind and properties of the food being preserved. Thus, it would have been customary for an artisan of ordinary skill, to adjust the amount of sodium alginate coupled with  $\beta$ -limit dextrin in the composition, in order to achieve the desired degree of preservation. Thus, absent some demonstration of unexpected results from the claimed parameters, optimization of any of these parameters would have been obvious at the time of Applicants' invention.

All claims have been rejected; no claims are allowed.

#### **CORRESPONDENCE**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

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/Jeffrey T. Palenik/  
Examiner, Art Unit 1615

/Robert A. Wax/  
Supervisory Patent Examiner, Art Unit 1615